of the amendments above and the following comments.

At the outset, Applicants respectfully request that the withdraw the finality of the final rejection. The final rejection contains a new obviousness rejection on page 3 thereof, which is based on Bourke et al. ("Bourke"), U.S. Patent No. 5,637,320. This new rejection was not contained in the previous Office Action dated April 10, 2000. Further, the Request for Reconsideration filed on August 8, 2000, did not contain any claim amendments. Consequently, there was nothing in Applicants' previous response that necessitated this new ground of rejection. Therefore, the open final rejection should not have been made final, and Applicants respectfully request that the Examiner withdraw the finality of such final rejection. *See, Manual of Patent Examining Procedure,* § 706.07(a) ("Under present practice, second or any subsequent actions on the merits shall be final, *except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims* nor based on [new] information submitted in an information disclosure statement.")

In case the finality is maintained, then Applicants next wish to address the showing required under 37 CFR § 1.116(a) regarding why the amendments above are necessary and were not presented earlier. The amendments were responsive to the Examiner's comment towards the bottom of page 2 of the final rejection that "Applicant does not claim that the analgesics are different," and are believed necessary to overcome the Examiner's theory of technical

anticipation. The amendments were not presented earlier because, as indicated, they are responsive to the Examiner's comment in the final rejection, and, since this is the first substantive response to the final rejection, these amendments could not have been presented earlier. In view of the foregoing, Applicants respectfully request that the Examiner enter and consider the amendments above.

Applicants submit that the amendments above do not introduce new matter. Although the specification as filed does not utilize the words "wherein element A and element B are different chemical compounds," this concept is clearly conveyed to persons skilled in the art by the specification as filed. Thus, the lists of elements A and B on page 2 are believed to be mutually exclusive, and the instant examples show different chemical compounds being used as elements A and B. Accordingly, nowhere can a person skilled in the art take from the instant specification that elements A and B could be the same chemical compound. Instead, such persons are clearly left with the impression that elements A and B are different chemical compounds. Therefore, amendment of the claims to reflect this fact does not introduce new matter. *See, e.g., In re Anderson,* 176 USPQ 331, 336 (CCPA 1973), for the proposition that in determining whether an amendment to a claim constitutes new matter, the question is not whether the added *word* is a word that is used in the application as filed, but whether the *concept* embodied by the added word is present in the original specification. *See, also, Ex parte Parks,* 30 USPQ2d 1234, 1236-7 (BPAI 1993). In view of the foregoing, Applicants submit that the amendment to claim 1 does

not introduce new matter. An early notice to that effect is earnestly solicited.

Claims 1, 3 and 4 were finally rejected under 35 USC § 102(e) as being anticipated by Bourke.

Claims 1-4 were also finally rejected under 35 USC § 103(a) as being obvious over Bourke.

In response to *both* rejections, Applicants point out that the Examiner's rejections are critically dependent on the same chemical compound, namely Naproxen, being used both as the "locally acting analgesic" and as the "systemically acting analgesic." There is absolutely no teaching or suggestion in Bourke to use *different* chemical compounds as the "locally acting analgesic" and as the "systemically acting analgesic," as required by the present claims. Accordingly, the present claims cannot be anticipated by or obvious over Bourke.

Further, the foregoing analysis presumes, merely for the sake of argument, that the Examiner's characterization of Bourke's teachings is correct. However, Applicants believe that the Examiner's characterization of Bourke's teachings is actually incorrect. In point of fact, Applicants previously requested that the Examiner explain where the prior art teaches Naproxen has both "locally acting" and "systemically acting" properties. Possibly, the statements towards

the bottom of page 2 of the Office Action are intended to be an explanation. If so, then it appears that the Examiner has improperly generalized "relatively immediate therapeutic response" to be the same as "locally acting." However, even a systemic therapeutic response could be "relatively" immediate. Accordingly, the rejection is still without any evidence that Naproxen, which is a systemically acting analgesic, would have been considered by persons skilled in the art to be a locally acting analgesic. Thus, there is a clear gap in the Examiner's reasoning, which has not been bridged, and, for these reasons, Applicants submit that the Examiner would be fully justified to reconsider and withdraw both rejections.

Further, as can be gathered from Bourke at column 1, line 60, to column 2, line 2, there is described a Naproxen formulation, wherein the drug is formulated in two different manners. In a first portion, the drug is formulated such that a controlled release of Naproxen is obtained leading to a maintenance of therapeutically effective blood levels over 24 hours. In a second portion, the Naproxen is formulated such that it is immediately *released.* However, this does not mean that an immediate onset of action caused by Naproxen can be observed. Namely, as already described in the present application, page 2, line 25, Naproxen belongs to the group of systemically acting analgesics. As also described in the present application, page 1, lines 21 to 23, such systemically acting analgesics reach their maximum activity not until after about 1 to 2 hours. Moreover, as described in the original description, page 3, lines 7 to 10, such systemic analgesics show a significant onset of action only after 15 min. lasting for up to 24 hours.

Therefore, regardless in which way Naproxen is formulated, it does not show an almost immediate onset of action. This, however, is required according to the present invention for the combination element A, i.e. the locally acting analgesic. As explained in the original description page 1, lines 30 to 32, the element A has to show a significant onset of action within a period of at most 10 min., preferably within a much shorter period of time. This cannot be realized by the use of Naproxen as element A since as explained above Naproxen by its nature is not able to cause such an immediate onset of action.

In view of the foregoing, Applicants respectfully request that the Examiner reconsider and withdraw these rejections.

In the event that these rejections are maintained, then Applicants renew their request, made above, that the finality of these rejections be withdrawn.

Applicants believe that the foregoing constitutes a bona fide response to all outstanding objections and rejections.

Applicants also believe that this application is in condition for immediate allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to

telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

Early and favorable action is earnestly solicited.

Respectfully submitted,

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the foregoing Amendment under 37 CFR § 1.116 (8 pages total) is being facsimile transmitted to the United States Patent and Trademark Office on the date indicated below:

Date: December 19, 2000

By _____
Kurt G. Briscoe